DEC 19 2013

510(K) SUMMARY FOR THE VENACURE EVLT NEVER TOUCH TRE' SHEATH INTRODUCER AND VENACURE EVLT NEVER TOUCH PROCEDURE KIT

Date Prepared: 19-November-2013

A. Sponsor:

AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury, NY 12804

B. Contact:

Teri Juckett
Manager, Global Regulatory Affairs
Tel: 518-795-1142
Fax: 518-742-4323
Email: tjuckett@angiodynamics.com

or

Lorraine M. Hanley
Vice President, Global Regulatory Affairs
Tel: 508-658-7945
Fax: 508-658-7976
Email: lhanley@angiodynamics.com

C. Device Name:

Trade Name:	VenaCure EVLT Tre' Sheath VenaCure EVLT NeverTouch Procedure Kit
Common/Usual Name:	Greater Saphenous Vein Procedure Kit
Classification Name:	Laser Instrument, Surgical Powered (21CFR§878.4810, Class II, Pro-Code GEX)
Classification Panel:	General Hospital & Plastic Surgery

D. Predicate Device:

Trade Name:	VenaCure EVLT Tre' Sheath VenaCure EVLT NeverTouch Procedure Kit
Common/Usual Name:	Greater Saphenous Vein Procedure Kit
Classification Name:	Laser Instrument, Surgical Powered (21CFR§878.4810, Class II, Pro-Code GEX)
Classification Panel:	General Hospital & Plastic Surgery
Premarket Notification:	K102796 and K100199

E. Device Description:

The VenaCure EVLT Tre' Sheath is a 4F sheath used during endovascular venous laser treatment procedures. The sheath is used as a conduit for placing a laser fiber. The product will be offered in 25, 45, 65 and 90cm lengths. The VenaCure EVLT Tre' Sheath will be provided both as a standalone product and also packaged with a variety of procedural accessories.

F. Intended Use:

The VenaCure EVLT Tre' Sheath and VenaCure EVLT NeverTouch Procedure Kits are indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

G. Summary of Similarities and Differences in Technology Characteristics and Performance:

The proposed device has similar materials, design, components, and technical characteristics as the predicate device.

H. Performance Data:

The proposed VenaCure EVLT Tre' Sheath and VenaCure NeverTouch EVLT Procedure Kit are substantially equivalent to the specified predicate devices based on a comparison of technological characteristics and the results of non-clinical performance testing, which include:

- Visual Inspection
- Sheath / Dilator Interface (Length and Force to Withdraw)
- Depth Mark Spacing
- Surface Friction Testing
- Static Pressure Testing
- Luer Lock Fitting Testing
- Tensile Test – Hub Joints
- Needle Tensile
- Fiber Output
- Biocompatibility per ISO 10993-1

I. Conclusion:

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

AngioDynamics Incorporated
Ms. Lorraine M. Hanley
Vice President, Global Regulatory Affairs
603 Queensbury Avenue
Queensbury, New York 12804

December 19, 2013

Re: K133561
Trade/Device Name: VenaCure EVLT Tre' Sheath
VenaCure EVLT NeverTouch Procedure Kit
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 19, 2013
Received: November 26, 2013

Dear Ms. Hanley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number K133561

Device Name: VenaCure EVLT Tre' Sheath
VenaCure EVLT NeverTouch Procedure Kit

Indications for Use:

The VenaCure EVLT Tre' Sheath and VenaCure EVLT NeverTouch Procedure Kits are indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

Prescription Use: ☒ (Per 21 CFR Subpart D

And/Or

Over-the-Counter Use: ☐ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
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(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number _K133561_____